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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,334	07/18/2000	MICHEL DROUX	PH-98/080	6869
7590	12/19/2003		EXAMINER	
CONNOLLY BOVE LODGE & HUTZ 1220 MARKET STREET P O BOX 2207 WILMINGTON, DE 19899-2207			KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER	1638		

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,334	DROUX ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6,9-11,15-23,25,26,31-62,65-71 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,15,16,21,22 and 31-59 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6,9,17-20,25,26,60-62,65-71 and 74-77 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 6, 9, 10-11, 15-23, 25-26, 31-62, 65-71 and 74-77 are pending.
2. Claims 10-11, 15-16, 21-22 and 31-59 remain withdrawn from consideration, as being drawn to nonelected inventions. Applicant is reminded that complete reply to a final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. Claims 6, 9, 17-20, 23, 25-26, 60-62, 65-71 and 74-77 are examined to the extent they read on SEQ ID NO:1, which encodes the *Arabidopsis* cytoplasmic SATase, SAT3.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejection of claims 2-6, 9, 13, 17, 19-20, 24, 26, 60-63, 65 and 72-73 under 35 U.S.C. 103(a) as being unpatentable over Saito et al (1994, Plant Physiol. 106:887-895) in view of each of Noji et al (1998, J. Biol. Chem. 273:32739-32745) and Ruffet et al (1995, Eur. J. Biochem 227:500-509) is withdrawn in light of applicant's amendments to limit the method to one consisting of overexpressing serine acetyltransferase.
6. The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Saito et al (1994, Plant Physiol. 106:887-895) in view of each of Noji et al (1998, J. Biol. Chem. 273:32739-32745) and Ruffet et al (1995, Eur. J. Biochem 227:500-509) as applied to claims 2-6, 9, 13, 17, 19-20, 24, 26, 60-63, 65 and 72-73 above, and further in view of Svab et al (1993, Proc. Natl. Acad. Sci USA 90:913-917) is withdrawn in light of applicant's amendments to limit the method to one consisting of overexpressing serine acetyltransferase.
7. The rejection of claims 23, 25 and 66-71 under 35 U.S.C. 103(a) as being unpatentable over (1994, Plant Physiol. 106:887-895) in view of each of Noji et al (1998, J. Biol. Chem.

273:32739-32745) and Ruffet et al (1995, Eur. J. Biochem 227:500-509) as applied to claims 2-6, 9, 13, 17, 19-20, 24, 26, 60-63, 65 and 72-73 above, and further in view of LeBrun et al (1999, RE 36,449) is withdrawn in light of applicant's amendments to limit the method to one consisting of overexpressing serine acetyltransferase.

Claim Objections

8. Claims 9, 18, 71, 75 and 77 are objected to because of the following informalities:

In claims 9, 75 and 77, line 2, a comma should be inserted after "SAT3".

In claim 18, line 4, --wherein the DNA sequence-- should be inserted after "acetyltransferase,".

In claim 71, line 4, "to the" is repeated twice.

Claim Rejections - 35 USC § 112

9. Claims 6, 17-20, 23, 25-26, 60-62, 6571, 74 and 76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of increasing the production of cysteine, glutathione, methionine and sulfur derivatives in a plant by transformation with a gene encoding an Arabodopsis cysteine-insensitive SATase operably linked to some transit peptides, does not reasonably provide enablement for methods of increasing the production of cysteine, glutathione, methionine and sulfur derivatives in a plant by transformation with a gene encoding any cysteine-insensitive SATase operably linked to transit peptides comprising plant plastid transit peptides and N-terminal portions of mature plastid proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope

with these claims. The rejection is different from the rejection set forth in the Office action mailed 29 April 2003, as applied to claims 2-3, 5-6, 13, 17-20, 23-26, 60-61 and 63-72.

Applicant's arguments filed 2 September 2003 have been fully considered but do not apply to this new rejection.

The claims are broadly drawn to methods of increasing the production of cysteine, glutathione, methionine and sulfur derivatives in a plant by transformation with a gene encoding any cysteine-insensitive SATase operably linked to transit peptides comprising plant plastid transit peptides and N-terminal portions of mature plastid proteins.

The instant specification, however, only provides guidance for a method of assaying the inhibition of pea SATase isoforms by cysteine to show that the mitochondrial form is severely inhibited by cysteine, the cytoplasmic form is moderately inhibited and the cytosolic form is not inhibited at all (example 1); the specification states that in *Arabidopsis* the chloroplast enzyme is cysteine-insensitive and that which form is insensitive and which sensitive is plant dependent (example 1); analysis of the mode of inhibition by cysteine to show that it a non-competitive inhibitor (example 1); isolation of the cytoplasmic SATase (SAT3, SEQ ID NO:1, which encodes SEQ ID NO:2) from *Arabidopsis* by functional complementation of an *E. coli* mutant (example 2); overexpression of SAT3 in *E. coli* and isolation of the protein to show it is cysteine-insensitive (example 3); isolation of other SATases from *Arabidopsis*, including SAT3' (SEQ ID NO:3), another cytosolic form (example 4), SAT1' (SEQ ID NO:5), a cytosolic form (examples 5 and 11), SAT1 (SEQ ID NO:7), a mitochondrial form (example 5), SAT2 (SEQ ID NO:9) a chloroplastic form (example 7), and SAT4 (SEQ ID NO:11), another chloroplastic form (example 8); overexpression of SAT1 in *E. coli* and isolation of the protein to show it is cysteine-insensitive (example 6). The specification provides guidance for the transformation of tobacco

with a nucleic acid encoding one of these SATases with and without the OTP (examples 9-10), that plants transformed with a nucleic acid encoding cysteine-insensitive SAT3, SAT1' or SAT1 have increased levels of cysteine, glutathione and methionine, compared to untransformed plants (examples 11-13).

The specification fails to provide guidance for nucleic acids encoding a cysteine-insensitive plant SATase other than SEQ ID NO:2 or a cysteine-insensitive bacterial SATase other than that from *E. coli* or for transit peptides comprising plant plastid transit peptides and N-terminal portions of mature plastid proteins other than OTP.

Given the claim breadth and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

10. Claims 6, 17-20, 23, 25-26, 60-62, 6571, 74 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is different from the rejection set forth in the Office action mailed 29 April 2003, as applied to claims 4-5 and 60. Applicant's arguments filed 2 September 2003 have been fully considered but do not apply to this new rejection.

The claims are broadly drawn to methods of using nucleic acid encoding any cysteine-insensitive SATase or transit peptides comprising plant plastid transit peptides and N-terminal portions of mature plastid proteins. In contrast, the specification only describes nucleic acids encoding a plant cysteine-insensitive SATase from *Arabidopsis*, a cysteine-insensitive bacterial SATase from *E. coli* and the OTP transit peptide. Applicant does not describe other DNA

molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the method of using the sequences to increase the production of cysteine, glutathione, methionine and sulfur derivatives in a plant is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

11. Claims 6, 9, 17-20, 23, 25-26, 60-71 and 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 29 April 2003, as applied to claims 2-6, 9, 13, 17-20, 23-26 and 60-73. Applicant's arguments filed 2 September 2003 have been fully considered but they are not persuasive.

It is not clear in claim 60 what the practitioner of the invention must do to overexpress serine acetyl transferase in plants or plant cells already transformed with a nucleic acid encoding the enzyme. No step is drawn to inducing an inducible promoter, for example.

Applicant urges that overexpressing and expressing are not indefinite and that one of skill in the art would know what it means to express or overexpress a protein, which refers to the production of protein by cells or organisms transformed with a nucleic acid (response pg 10-11).

This is not found persuasive because it is not clear what the practitioner of the invention must physically do to express or overexpress the protein. It is suggested that the method be made one whose steps comprise transforming a plant cell, and optionally regenerating a plant from the plants cell, whereby the plant cell or the plant over expresses serine acetyltransferase and has an increase in production of cysteine, glutathione, methionine or sulfur-containing derivatives of methionine relative to a nontransformed plant or plant cell.

It is not clear in claim 74, part (b), and claim 76, part (c), what the practitioner of the invention must do to express serine acetyl transferase in plants or plant cells already transformed with a nucleic acid encoding the enzyme. No step is drawn to inducing an inducible promoter, for example.

12. Claims 6, 9, 17-20, 25-26, 60-62, 65-71 and 74-77 are free of the prior art, given the failure of the prior art to teach or suggest a method of increasing the production of cysteine and other sulfur-containing compounds in a plant or plant cells by transformation with a construct encoding a cysteine-insensitive SATase.

13. Claims 9, 75 and 77 would be allowable if rewritten to overcome the objection and the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059.

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The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Sometime in January 2004, the examiner's phone number will change to 571-272-0801.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

December 9, 2003

A handwritten signature in black ink, appearing to read "Anne R. Kubelik".